

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OKLAHOMA**

In re: Genentech, Inc., Herceptin  
(Trastuzumab) Marketing and Sales  
Practices Litigation

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MDL Docket No. 16-MD-2700

Document Relates to:  
**All Cases**

**DEFENDANT’S STATUS REPORT ON PREEMPTION DISCOVERY**

In an effort to steer the parties towards resolution of discovery issues raised during a hearing on November 17, 2016, the Court suggested that Plaintiffs assemble a list of proposed facts regarding obstacle preemption arguments that they hoped further discovery would permit them to prove. When the parties were unable to agree on a set of proposed facts Plaintiffs could submit in lieu of further discovery on obstacle preemption, the Court—recognizing that simply accepting certain things as true would unfairly handicap Genentech<sup>1</sup>—asked that the proposed facts be restated as “issues” and instructed the parties to continue discussions regarding the proposed issues and the process by which they would be addressed in the context of Genentech’s pending summary judgment motion.<sup>2</sup>

Following the December 14, 2016 hearing, the parties were able to agree to the removal of three items on Plaintiffs’ list<sup>3</sup> and the revision of language on certain other items. Although some progress was made with respect to the list of proposed issues,<sup>4</sup> the process for addressing them may pose a greater obstacle to agreement.

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<sup>1</sup> Transcript of December 14, 2016 Hearing (“Dec. 14 Trans.”) at 26:5–26:21.

<sup>2</sup> Dec. 14 Trans. at 36:7–36:23, 37:9–37:11.

<sup>3</sup> Plaintiffs’ agreed to remove item Nos. 17, 30, and 31 (all of which were discussed during the November 17, 2016 hearing).

<sup>4</sup> The current list of “issues” is attached as Exhibit 1 to Genentech’s concurrently filed Motion for Order Requiring Plaintiffs to Comply with Federal Rule of Civil Procedure 56(d) and Brief in Support.

Throughout the meet-and-confer process, Genentech maintained that it should be able to respond in any reply to a number of the items on Plaintiffs' list of "issues." Genentech's position is consistent with statements from the Court indicating that restating proposed facts as "issues" would leave in place Genentech's ability to argue that certain things are: (1) legal questions; (2) irrelevant facts; or (3) established by evidence already in the record.<sup>5,6</sup> While Plaintiffs acknowledge that Genentech may argue that an issue is legal rather than factual or that it is not material to the Court's determination of obstacle preemption, Plaintiffs have proposed a procedure (attached as Exhibit 2 to Genentech's concurrently filed Motion for Order Requiring Plaintiffs to Comply with Federal Rule of Civil Procedure 56(d) and Brief in Support) that effectively requires Genentech to agree that all "issues" be accepted as true (*i.e.*, resolved in Plaintiffs' favor)<sup>7</sup>, and entirely forecloses Genentech's ability to present any evidence whatsoever or argue in its reply that an issue has already been established to the contrary.<sup>8</sup> Indeed, Plaintiffs even proposed that Genentech should not be allowed to ask the Court to take judicial notice of any facts, *e.g.*, what was approved by the FDA. Genentech raised concerns with and invited further discussion regarding Plaintiffs' proposed procedure on January 4, 2017 (attached as Exhibit 3 to Genentech's concurrently filed Motion for Order Requiring Plaintiffs to

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<sup>5</sup> See Dec. 14 Trans. at 26:5–27:7.

<sup>6</sup> In their Status Report on Preemption Discovery (Dkt. No. 160), Plaintiffs appear to suggest that Genentech wishes to present new evidence in a reply and that would be unfair to Plaintiffs if they are denied discovery. Plaintiffs misrepresent Genentech's position. Throughout and the meet and confer process, Genentech has never suggested that it wants to present new evidence. Instead, Genentech has repeatedly said it should be able to point to evidence already in the record.

<sup>7</sup> "In their Response, Plaintiffs may argue that under the standard of review applicable to summary judgment motions, the Disputed Issues must be resolved in Plaintiffs' favor for purposes of the Refiled Motion. Defendant will not oppose this position [in] its Reply Brief (the 'Reply')." See Ex. 2 at para. 4.

<sup>8</sup> "In its Reply, Defendant may not argue a Disputed Issue is actually undisputed and may not introduce summary judgment evidence related to that issue or intended to show a Disputed Issue is undisputed. Defendant will not introduce any new evidence in connection with its Reply and will not ask the Court to take judicial notice of any facts." See Ex. 2 at para. 6.

Comply with Federal Rule of Civil Procedure 56(d) and Brief in Support). Genentech further proposed that presentation of Plaintiffs’ proposed issues be governed by Federal Rule of Civil Procedure 56(d). Plaintiffs have stated that they disagree.

The limitations set forth in Plaintiffs’ proposed procedure unfairly impair Genentech’s ability to support its summary judgment motion. Plaintiffs’ procedure, for example, prevents Genentech from citing to the previously-produced final labeling—which FDA approved and which has never expressed the concentration of reconstituted solution using a decimal—to address Plaintiffs’ proposed issue regarding whether “[t]he FDA instructed Genentech to accurately state the concentration of reconstituted Herceptin, including using a decimal for increased accuracy.”<sup>9</sup> It also prevents Genentech from citing to previously-produced evidence of FDA’s approval of Herceptin and its final labeling to address Plaintiffs’ proposed issue regarding whether “[t]he FDA did not examine whether the concentration of reconstituted Herceptin as reported on the Herceptin labeling was accurate.”<sup>10</sup> Remarkably, Plaintiffs’ proposed procedure even goes so far as to prohibit Genentech from seeking judicial notice.<sup>11</sup>

Despite the impasse, these efforts have not been in vain. Although Plaintiffs had provided some explanation of their potential arguments in a prior joint submission, creating the list of issues has allowed the parties to more fully understand their relative positions and has narrowed the focus to obstacle preemption. As a result of this process of creating a list of “issues,” Plaintiffs have finally articulated what discovery they believe they need before responding to obstacle preemption arguments in the pending summary judgment motion. Genentech submits that Rule 56(d) is the appropriate mechanism for resolving whether

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<sup>9</sup> Ex. 1 at No. 24.

<sup>10</sup> Ex. 1 at No. 18.

<sup>11</sup> See Ex. 2 at para. 6.

additional discovery is necessary. Indeed, Rule 56(d) was designed for this very situation.<sup>12</sup>

Accordingly, Genentech has concurrently filed a Motion for Order Requiring Plaintiffs to Comply with Federal Rule of Civil Procedure 56(d) and Brief in Support.

Respectfully Submitted,

/s/ William W. O'Connor

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<sup>12</sup> Plaintiffs' proposed procedure notes that Rule 56(d) "provides an alternative method to address a situation where facts are unavailable to the nonmovant." See Ex. 2 at para. 8(b).

**CERTIFICATE OF SERVICE**

I hereby certify that on this 9th day of January, 2017, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing and distribution of the notification of such filing to all counsel of record as required in the Court's Practice and Procedure Order (MDL Doc. #6 at ¶5).

/s/ William W. O'Connor

William W. O'Connor